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EXAMINER	
FRAZIER, BARBARA S	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
05/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	09/743,577	SCHLACHTER, HERBERT	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13,17-19,22-43 and 45-47* is/are pending in the application.

4a) Of the above claim(s) *41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13,17-19,22-40 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 2-13, 17-19, 22-43, and 45-47 are pending in this application. Addition of new claims 45-47 is acknowledged. Claims 1, 14-16, 20, and 21 stand canceled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/13/09 has been entered.

Election/Restrictions

3. In the response filed 3/13/09, Applicants state that they are not arguing that the species are obvious variants, and maintain that the Examiner still has no grounds to require an election of species because there is no serious burden on the Examiner to examine the indications described in claims 41-43, and presumes that the Examiner has already searched the group of disorders in claims 41-43.

4. The Examiner points out that the restriction requirement has already been made FINAL. That said, a serious burden does, in fact, exist, for reasons set forth in the

previous Office action mailed 10/19/07 (see paragraph bridging pages 2 and 3). Thus, the finality of the restriction requirement is maintained.

5. Claims 41-43 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/19/08.

6. Claims 2-13, 17-19, 22-40, and 45-47 are examined.

Information Disclosure Statement

7. The information disclosure statement (IDS) submitted on 11/12/08 has been considered by the examiner.

Response to Arguments to Prior Art

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. However, since the Examiner has retained the references of Oliver, De Paoli, Horrobin, and Burke, the Examiner will address pertinent arguments pertaining to said references.

In response to applicant's arguments against the references individually, specifically, that there is no disclosure in Oliver pointing to a combination of zinc oxide with an amino acid, and Oliver does not explicitly teach polyphenols or the use of 2 to 50 wt.% of at least one secondary plant substances, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of

references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to Applicant's argument that the effect of the composition of De Paoli is based on the use of acetylglucosamine and glucuronic acid either alone or combined, it is noted that Applicant's use of the open-ended term "comprising" allows for the presence of acetylglucosamine and glucuronic acid, as well as an amino acid and polyphenols, as taught by De Paoli.

Applicant argues that there is no explicit disclosure in De Paoli of a combined use of amino acids in pure form with a polyphenol required by present claim 2. Applicants also argue that none of the examples of De Paoli contains a terpene, triterpene, saponine, isoflavonoid or flavonoid, and only preparation example 3 comprises proline, and thus one of skill would not know which "synergists" to choose.

This argument is not persuasive. Only six classes of compounds are taught as synergists by De Paoli, and amino acids and compounds which are polyphenols are two of the six classes. Further, De Paoli teaches that two or more of these synergists may be present in the composition (col. 3, line 54 - col. 4, line 4). Thus, it would be within the purview of the skilled artisan to select an amino acid and polyphenols as the two or more synergists by routine experimentation, in order to optimize properties of the resultant composition, such as moisturizing action, anti-aging action, and anti-cellulitis action, as well as ability to treat skin conditions, such as acne (see col. 5, lines 13-36). Additionally, De Paoli teaches that the amino acids may be selected from both dextrorotatory and levorotatory form and the related racemic mixtures, and thus are in

"pure form". Regarding the examples, it is noted that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

In response to applicant's argument that the references fail to show certain features of applicant's invention, specifically, that there is nothing in the documents which points to a composition useful as a key for cell membranes, it is noted that the features upon which applicant relies (i.e., a composition useful as a key for cell membranes) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regardless, since the composition of the combined references comprises the same components of the composition of the claimed invention, one skilled in the art would reasonably expect the composition of the combined references to also be useful as a key for cell membranes. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In response to Applicant's arguments regarding Horrobin et al, specifically, that Oliver does not use E-series prostaglandins, and therefore one of skill in the art would not pick out an optional component of a composition of Horrobin and add it to a composition of Oliver, it is noted that Horrobin et al do not teach that E-series

prostaglandins are in their composition, but rather that the *in vivo* level of E-series prostaglandins and especially prostaglandin E1 (which has anti-inflammatory activity) may be increased by incorporating dihomo-γ-linolenic acid and/or its bioprecursors such as γ-linolenic acid and linoleic acid into compositions for treating lesions (col. 2, lines 43-53). Since anti-inflammatory activity would be desired for treating the inflammatory response associated with skin lesions, as taught by Horrobin et al, one skilled in the art would be motivated to add dihomo-γ-linolenic acid to compositions for treating skin lesions.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that there is no suggestion that Horrobin would be useful to increase microcirculation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to Applicant's arguments that Burke et al teach that particularly preferred peroxides are hydrogen peroxide and benzoyl peroxide, that neither zinc peroxide nor sodium peroxide is mentioned in Burke et al as a preferred peroxide or a particularly preferred peroxide, and that it is not comprehensible why there should be any motivation for a person skilled in the art to replace a preferred peroxide or a particularly preferred peroxide in expectation of any improvement, it is noted that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169

USPQ 423 (CCPA 1971). In the instant case, Burke et al teach that hydrogen peroxide, zinc peroxide, and sodium peroxide all function as disinfectants in compositions to be applied to the skin, and thus are functionally equivalent to one another.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 2, 5-11, 17-19, 26-40, 45, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oliver (US Patent 5,869,062) in view of De Paoli (US Patent 6,147,054).

The claimed invention is drawn to a preparation for topical application comprising the components (a) at least one salt selected from alkali metal salts, alkaline earth metal salts, and other minerals, (b) at least one individual amino acid in pure form, (c) zinc oxide and an inorganic peroxide, and (d) 2 to 50 % by weight of at least one

secondary plant substance selected from the list in claim 2 (see claim 2). Applicants have elected polyphenols as the secondary plant substance (claims 2 and 45).

Oliver teaches a skin treatment composition for skin-related problems, especially infection, acne and blemishes (see col. 1, lines 4-11 and claims). The composition comprises 8-20% calamine (zinc oxide with 0.5% ferric oxide); 0.05-3% antioxidant; and 0.25-4% of an anti-bacterial. Oliver also teaches that a peroxide, such as hydrogen peroxide, and zinc oxide, may be added to the formulation (col. 3, lines 5-15).

Oliver does not specifically teach the presence of an amino acid or polyphenols in the formulation.

De Paoli teaches a composition that is applied to intact or injured skin (col. 1, lines 5-20). The composition comprises various active ingredients, defined as synergists; two or more of these synergists may be present in the composition (col. 3, line 54 - col. 4, line 4). Two of the six classes of synergists described include amino acids (alanine arginine, aspartic acid, asparagine, cysteine, glutamic acid, glutamine, glycine, histidine, leucine, isoleucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, or valine); and chemical substances from plants, including triterpenes, saponins, isoflavonoids, alcohol flavonoids including anthocyanidins, which are polyphenols (see col. 4, lines 43-67). (Other classes of synergists are carboxylic acids – col. 3, lines 57-67; vitamins – col. 4, lines 8-26; plant extracts - col. 4, lines 26-42; and polysaccharides - col. 5, lines 5-10). The composition is used to treat acne, increase circulation, dematitides, heal wounds, etc. see column 5, lines 20-35. Based on the disclosure of DePaoli, it would be within the purview of the

skilled artisan to select an amino acid and polyphenols as the two or more synergists by routine experimentation, in order to optimize properties of the resultant composition, such as moisturizing action, anti-aging action, and anti-cellulitis action, as well as ability to treat skin conditions, such as acne (see col. 5, lines 13-36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Oliver and DePaoli; thus arriving at the claimed invention. One would have been motivated to combine the composition of DePaoli with the composition of Oliver because the composition of DePaoli provides not only skin treatment of conditions such as acne, as also taught by Oliver, but also provides the additional benefits of improving aesthetic parameters of the skin, such as moisturizing action, an anti-aging action, anti-wrinkle action, elasticizing action, and anti-cellulitis action (col. 5, lines 13-22). Further, a skilled artisan would have been motivated to combine the teachings with a reasonable expectation of success since both references teach the treatment of acne. Therefore, "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Regarding the amount of polyphenols, De Paoli teaches that these substances may be present in an amount of 0.01-20% (col. 4, lines 56-57). This amount range overlaps that of the claimed invention. One skilled in the art would be motivated to

manipulate the amount of polyphenols from within said ranges by routine experimentation, in order to optimize properties of the resultant composition, such as moisturizing action, anti-aging action, and anti-cellulitis action, as well as ability to treat skin conditions, such as acne (see col. 5, lines 13-36).

Regarding the preparation being for topical application (claims 2, 17, and 45), Oliver teaches that the composition is applied to skin (col. 1, line 3), and De Paoli teaches that the composition is for external use, to be applied either on intact or injured skin (col. 1, lines 9-12).

Regarding claims 5-9, Oliver teaches that the composition comprises ferric oxide (col. 2, lines 14-16), vitamins (col. 2, lines 25-28), the humectant glycerin (col. 2, lines 48-50), natural antibacterial product (col. 2, lines 28-37), and water as a solvent/base (abstract).

Regarding claim 10, Oliver teaches 8-20% calamine (zinc oxide with 0.5% ferric oxide), 8-20% zinc oxide, and 3-8% peroxide (col. 2, lines 14-17 and col. 3, lines 5-15). Additionally, De Paoli teaches amounts of 0.001-20% amino acids (col. 5, lines 1-4). These amount ranges overlap those of the claimed invention. One skilled in the art would be motivated to manipulate the amounts of said components from within said ranges by routine experimentation, in order to optimize properties of the resultant composition, such as ability to treat skin conditions, such as acne, as well as moisturizing action, anti-aging action, and anti-cellulitis action.

Regarding claim 11, Oliver teaches the presence of calamine (zinc oxide with 0.5% ferric oxide), and De Paoli teaches the presence of amino acids (alanine arginine,

aspartic acid, asparagine, cysteine, glutamic acid, glutamine, glycine, histidine, leucine, isoleucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, or valine).

Regarding claims 18, 19, and 26-39, the compositions of Oliver and De Paoli are applied to the skin for treatment of various skin conditions, and therefore would be suitable for use as a cosmetic or a pharmaceutical composition.

Claims 40 of the claimed invention is drawn to a method for treating skin conditions listed in claim 40, comprising topically administering to a patient in need of such treatment a pharmaceutically effective amount of the preparation as described in claim 2 or claim 3 (see claim 40). Applicants have elected cellulitis as the condition to be treated (claims 40 and 47).

The inventions of Oliver and De Paoli are delineated above. Oliver teaches that its composition is a skin treatment composition which clears up most skin-related problems, including rashes and blemishes, and names acne (col. 1, lines 3-12), but does not specifically teach that the rashes/blemishes to be treated are due to cellulitis. De Paoli teaches that its compositions may be used to treat acne, and also has anti-cellulitis action (col. 5, lines 13-27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and expect the composition to treat cellulitis. One would have been motivated to utilize the composition to treat cellulitis and reasonably expect success since De Paoli teaches that its composition treats both acne and cellulitis, and Oliver teaches that its composition treats acne and

generally teaches treatment of other rashes and blemishes. Since Oliver treats acne and generally treats rashes and blemishes, and the composition of De Paoli treats both acne and cellulitis, it would be prima facie obvious to use the composition of the combined references to treat cellulitis, absent evidence to the contrary.

12. Claims 3-11, 13, 22-40, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oliver (US Patent 5,869,062) in view of De Paoli (US Patent 6,147,054) as applied to claims 2, 5-11, 17-19, 26-40, 45, and 47 above, and further in view of Horrobin et al (US Patent 5,145,686).

Claims 3 and 4 of the claimed invention are drawn to a preparation for topical application comprising the same components as the preparation of claim 2, and further comprising at least one unsaturated fatty acid (claim 4), such as a polyunsaturated fatty acid of vegetable sources (claims 3 and 46). Applicants have elected polyphenols as the secondary plant substance (claims 3 and 46).

The invention of the combined references is delineated above (see paragraph 11).

The invention of the combined references does not teach the addition of at least one unsaturated fatty acid or polyunsaturated fatty acid of vegetable sources.

Horrobin et al teach topical pharmaceutical compositions for the treatment of lesions of the skin (abstract). Horrobin et al teach that lesions of the skin are generally associated with an inflammatory response, and, in turn, inflammation is believed to be due in part to excessive and/or defective production of certain prostaglandins and

related substances (col. 1, line 67 – col. 2, line 3). Horrobin et al further teach that the principal prostaglandin product derived from dihomo-γ-linolenic acid is prostaglandin E1 which exhibits the anti-inflammatory activity (col. 2, lines 11-13), and the in vivo level of E-series prostaglandins and especially prostaglandin E1 may be increased by incorporating dihomo-γ-linolenic acid and/or its bioprecursors such as γ-linolenic acid and linoleic acid into compositions for treating lesions (col. 2, lines 43-53).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add dihomo-γ-linolenic acid and/or its bioprecursors such as γ-linolenic acid and linoleic acid to the composition of the combined references; thus arriving at the claimed invention. One skilled in the art would be motivated to do so because the addition of dihomo-γ-linolenic acid and/or its bioprecursors such as γ-linolenic acid and linoleic acid to a composition for treating lesions provides the benefits of increasing the in vivo level of anti-inflammatory E1 prostaglandins, which would be desired for treating the inflammatory response associated with skin lesions, as taught by Horrobin et al. One would reasonably expect success from the addition of dihomo-γ-linolenic acid and/or its bioprecursors such as γ-linolenic acid and linoleic acid to the composition of the combined references because all of the references are drawn to topical compositions for the treatment of skin lesions, and Horrobin et al teach that dihomo-γ-linolenic acid may successfully be used with an amino acid (lysine) and a polyphenol (rutin) (for example, see Example 14).

Regarding claim 13, Oliver teaches that the composition is applied to skin (col. 1, line 3), and De Paoli teaches that the composition is for external use, to be applied either on intact or injured skin (col. 1, lines 9-12).

Regarding claims 22-25, the compositions of Oliver and De Paoli are applied to the skin for treatment of various skin conditions, and therefore would be suitable for use as a cosmetic or a pharmaceutical composition.

The limitations of claims 5-11, 26-40, and 47 are addressed above (see paragraph 11).

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oliver (US Patent 5,869,062) in view of De Paoli (US Patent 6,147,054), as applied to claims 2, 5-11, 17-19, 26-40, 45, and 47 above, or Oliver (US Patent 5,869,062) in view of De Paoli (US Patent 6,147,054) and further in view of Horrobin et al (US Patent 5,145,686) as applied to claims 3-11,13, 22-39, 46, and 47 above, and further in view of Burke et al (US Patent 5,693,318).

Claim 12 of the claimed invention is drawn to the preparation according to claim 2 or claim 3, wherein the inorganic peroxide is selected from the group consisting of zinc peroxide, sodium peroxide, potassium peroxide, calcium peroxide or magnesium peroxide (see claim 12).

The invention of the combined references is delineated above (see paragraphs 11 and 12). As stated above, Oliver teaches the use of peroxide such as hydrogen peroxide in the composition.

The invention of the combined references does not teach the instant peroxides claimed.

Burke et al teach cleansing compositions to be applied to the skin, comprising peroxides which act to disinfect the skin (abstract and col. 1, lines 15-30). Burke et al teach that useful peroxides include hydrogen peroxide, zinc peroxide, and sodium peroxide (col. 5, lines 38-41).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select zinc peroxide or sodium peroxide as the peroxide in the composition of the combined references; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because hydrogen peroxide, and zinc peroxide and sodium peroxide, are all disinfectant peroxides in compositions to be applied to the skin as taught by Burke et al, and therefore are functionally equivalent to one another. Therefore, it would be well within the purview of the skilled artisan to choose either compound as the peroxide of the composition of the combined references, since the prior art establishes the functional equivalency of zinc peroxide and sodium peroxide, and hydrogen peroxide.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611